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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,547	07/29/2003	Mark T. Marshall	P0011313.01	7482

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MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER	
BAYS, PAMELA M	
ART UNIT	PAPER NUMBER
3766	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,547	MARSHALL ET AL.	
	Examiner	Art Unit	
	Pamela M. Bays	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 7-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, and 7-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This Office Action is responsive to the Amendment filed on 14 July 2009 . As directed by the Amendment: Claim 1 has been amended, Claims 3-6 and 20-58 have been cancelled, and no claims have been added. Thus, Claims 1-2 and 7-19 are presently pending in this Application.

Terminal Disclaimer

2. The terminal disclaimer filed on 20 June 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of commonly owned Patent No. 7,191,016 has been reviewed and is accepted. The terminal disclaimer has been recorded. This terminal disclaimer had been previously withdrawn by the Applicant, and is now reinstated as directed by the Amendment dated 14 July 2009.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1,2, 7-10, and 16-18 stand rejected under 35 U.S.C. 102(b) as anticipated by Carson (US Patent Number 5,931,862, hereinafter Carson'862, previously cited).

5. Regarding claims 1 and 2, Carson'862 shows a medical electrical lead (Figs. 1 and 2, lead 12) comprising a first elongated body with a first elongated insulated conductor (elongated body 10', conductor 36) and a first connector at its proximal end (connector 22); a second elongated lead body with a second conductor (column 4, lines 52-63; Figs. 1 and 2, lead 10" and conductor 37) and a second connector at its proximal end (connector 24); a first low voltage electrode adapted for intimate contact with tissue to provide pacing stimulation (Figs. 2 & 3, distal pacing electrode 20, helical coil or tined formations); a second low voltage electrode joined to the lead body in proximity to the first electrode (underlying electrode 16); and a porous layer formed over the second electrode (porous tubular covering 10); wherein the outer surface of the second electrode (16) is recessed from the outer surface of the lead body (Fig. 2) and the outer surface of the porous layer (10) is isodiametric with the outer surface of the lead body (column 2, lines 39-44). Further regarding claim 1, Carson'862 discloses that the layer 10 covering the electrodes may be impregnated with collagen via perfusion, which is taken to reasonably disclose a sheet of collagen fibers, since the ePTFE sheet will be evenly distributed with the perfused collagen fibers (column 8, lines 50-65).
Carson '682 discloses that the porous layer is adapted to prevent chronic tissue ingrowth (column 2, lines 47-48). The prevention of chronic tissue ingrowth, which prevents the electrode from coming in direct contact with the tissue, is a sufficient and

effective means of preventing the electrode from stimulating tissue in proximity to the electrode. Alternatively, the pulse generator (Fig. 1, generator 11) of Carson'862 must inherently contain a control means used in the art, such as a microprocessor. That control means provides a means for preventing the second electrode from stimulating the tissue as the alternate state to control-driven stimulation of tissue. If the device is off, or the second electrode channel is powered down or in a blanked state, the control means is preventing the second electrode from delivering stimulation to the tissue.

6. Regarding claims 7-10, Carson'862 discloses a means to promote wetting comprising a wetting agent which can be a surfactant and a surface treatment of the porous layer (column 2, line 54 through column 3, line 26).

7. Regarding claim 16, Carson'682 discloses the invention as previously recited wherein the porous layer is adapted to prevent chronic tissue ingrowth (column 2, lines 47-48).

8. It is noted that the component of a second elongated lead body in the instant application does not distinguish over the device of Carson'682 because it shares a common functionality, and a device with a first and second lead bodies is a disclosed embodiment of the Carson'682 system (See Col. 3, Lines 44-56), with connector branches 22 and 24 with porous coverings 10' and 10" as a first and second lead body, containing the pacing/sensing electrodes and capable of being implanted in the cardiac vein (Col. 3, Lines 44-56) or the right ventricle (as shown in Figure 1).

9. ***Claims 1,2, 7-10, 11 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Krall et al. (WO 02/089909 A1, previously cited).***

10. Regarding claims 1 and 2, Krall et al. shows a medical electrical lead (Fig. 1, lead body 6) comprising a first elongated body with a first elongated insulated conductor and a first connector at the proximal end (connector 4, lead body leading to y-junction); a second elongated lead body comprising second elongated insulated conductor and second connector at the proximal end (the other connector 4 and lead segment; alternatively Fig. 2 coiled electrical conductor 14, second electrical conductor 16); a first low voltage electrode adapted for intimate contact with tissue to provide pacing stimulation (Fig. 2, distal tip electrode 10); a second low voltage electrode joined to the lead body in proximity to the first electrode (coiled electrode portion 8, coiled electrode 24); and a porous layer formed over the second electrode (porous thin film 30); wherein the outer surface of the second electrode (24) is recessed from the outer surface of the lead body (Fig. 2) and the outer surface of the porous layer (30) is isodiametric with the outer surface of the lead body (column 2, lines 39-44).

11. Regarding claims 7-10,11 and 16, Krall et al. discloses that the cover comprises a porous polymer (claim 1), preferably ePTFE (claim 8); is relatively thin, on the order of .13mm (or .005inches)thick (page 3, lines 5-6; page 10, lines 26 through page 11, line 4); is adapted to prevent chronic tissue ingrowth (page 3, lines 10-13); and comprises a means of wetting (claims 13-14, surfactant polyvinyl alcohol).

12. Claims 1,2 and 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Belden (US Patent 6,847,845, hereinafter Belden'845, previously cited).

13. The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

14. Regarding claims 1,2, and 16-19, Belden'845 discloses a medical system comprising an implantable medical device (80; Fig. 5); a first lead comprising a first elongated lead body with a first connector at the proximal end (lead 200, connector 206) implanted in a cardiac vein with a first electrode (12) adapted for intimate contact with tissue and a second lead comprising an elongate lead body with a connector at the proximal end (lead 201, connector 214) and a second electrode (16)with a porous layer (32) formed over the second electrode which may be isodiametric and comprised of ePTFE, silicone, or polyurethane (column 3, lines 20-25, 47-56) and adapted to prevent chronic tissue ingrowth (column 3, line 64 through column 4, line 5); and comprising a third high voltage electrode adapted for defibrillation stimulation (defibrillation coil 74).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 11-14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carson'862 in view of Hull et al. (US Patent 5,269,810, hereinafter Hull'810, previously cited).

17. Regarding Claims 11-14, Carson'862 shows the invention substantially as claimed, but does not disclose the thickness of the porous layer (2-9 mm) or the desired size range for the pores in that layer (0.4-50 microns). In the same problem solving area, Hull'810 teaches an electrode-covering layer that is about 0.13 mm (0.005 inches) thick with fibril length (i.e. internodal distance and pore size) of 10 microns for the advantages of being highly biocompatible, highly flexible, and long-lasting (column 3, lines 32-45; column 4, lines 1-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use similar structural criteria with the Carson'862 invention for the same advantages of biocompatibility, flexibility and long lifespan (motivation to combine provided by Hull et al., column 3, lines 32-45; column 4, lines 1-15).

18. ***Claims 12-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carson'862 in view of Soukup et al. (US Patent 5,466,252, previously cited).***

19. Carson'862 shows the invention substantially as claimed, but does not disclose the desired size range for the pores in that layer (0.4-50 microns). In the same field of endeavor, Soukup et al. teaches an implantable lead with a porous PTFE layer with preferred fibril lengths greater than 4 microns, and most preferably greater than 10 microns to provide the necessary amount of flexibility and extensibility for the intended application and to present an acceptable biocompatible surface to the blood chemistry

to which the outer surface of the lead will be exposed (column 2, lines 26-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use similar parameters for the lead body covering in the Carson'862 invention to provide the same advantages of flexibility and biocompatibility (motivation to combine provided by Soukup et al., column 2, lines 26-34).

20. Claim 19 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Carson'862 in view of Kroll (US Patent 6,327,498, previously cited).

21. Carson'862 shows the invention substantially as claimed, but does not disclose a third high voltage electrode adapted for defibrillation stimulation. In the same field of endeavor, Kro11'498 teaches a third electrode (Fig. 2, electrode 46) placed proximal to a second electrode (32) and distal to a first electrode (34) for the purpose of providing shocking stimulation pulses (column 7, lines 64-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a third electrode in the Carson'862 device for the same advantage of applying shocking stimulation (defibrillation) to the heart (motivation to combine provided by Kro11'498 column 7, lines 64-67).

Response to Arguments

22. The previous 35 USC 112 rejection of Claim 1 has been withdrawn due to the Applicant's Amendment.

23. The Terminal Disclaimer filed 20 June 2008 has been reinstated as requested by the Applicant in the Amendment dated 14 July 2009, thus overcoming the Double Patenting Rejection.

24. Applicant's arguments filed 14 July 2009 have been fully considered but they are not persuasive with respect to the Carson, Krall, and Belden references.

25. The Applicant argues that the Carson and Krall references do not show two lead systems. However, both references include embodiments wherein a second entirely separate lead is present (Carson, Col. 3, Lines 44-55, and Krall, Page 1, Lines 11-20). It is noted that each of the references is considered to read on the claims since independent claim 1 merely recites a first lead body with a first conductor and proximally located connector, and a second lead body with a second conductor and a proximally located second connector. Even a y-shaped connection reads on this limitation which merely requires that there be two separate proximal connectors connected to separate elongated bodies, which can clearly be seen in each of the references even in they y-shaped configuration. Additionally, the Belden reference even clearly shows a two-lead configuration in Fig. 2. Each of the references also reads on the further limitation that the first electrode is connected to the first conductor and the second electrode is connected to the second separate conductor as seen in the figures and referenced herein below. The claim language merely recites that the two electrodes be located at a first and second site and that they be connected to their respective connectors via their respective conductors, and doe not limit further the configuration of the enclosure at the electrode locations.

26. The Applicant further argues that, "the required porous layer over the second electrode is not disclosed in Belden...th[e] covering is not described as either porous or extending over the electrode." However the Examiner disagrees. Col. 3, Lines 64-65 of

Belden recites, "Shocking electrode 16 may be encased in a layer of porous PTFE material…" Thus Claim 1 stands rejected under Belden.

Conclusion

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pamela M. Bays whose telephone number is (571) 270-7852. The examiner can normally be reached on Monday-Friday, 9am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/P. B./
Examiner, Art Unit 3766